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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/836,870 | 04/17/2001 | Claude Jarkae Jensen | 10209.166 | 5882 |

7590 05/21/2002

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EXAMINER

YU, GINA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Applicati n No. 09/836,870 | Applicant(s) JENSEN ET AL. | |
| | Examiner Gina C. Yu | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 1,2 and 4-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachm nt(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Amendment filed February 21, 2002. Claims 1, 2, and 4-29 are pending. In view of the claim amendments by applicants, the claim rejections made under 35 U.S.C. § 112, 102, and 103 as indicated in the previous office action dated November 8, 2001 are withdrawn, and new rejections are made.

Response to Amendment

The amendment filed February 21, 2002 is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The statement that the present invention uses the extracts and concentrated extracts from several various parts of the Indian Mulberry or *Morinda citrifolia* plant ("noni"), such as the leaves, bark, roots, and other parts of the plant, while the fruit juice and oil are "preferably" used. See amended specification page 18, bridging paragraph. This statement is inconsistent with applicants' original disclosure that states, "The present invention utilizes the fruit juice and the oil extracted from the *Morinda citrifolia* plant." See original spec. p. 19, lines 8-9.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

A) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 2 and 4-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the original specification discloses the processing of noni fruit juice and refers to the specifically processed noni oil from the seed, because the specification, does not reasonably provide enablement for using other processed parts of the plant. There is no support in the original specification that the present invention employs other processed parts of the plant.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide enablement for how to make a composition comprising xeronine and Proxeronase in the amount of 0.001-80 percent by weight. While the specification discloses that xeronine and Proxeronase are present in noni, there is no guidance as to how one skilled in the art would go about determining the amount of the xeronine or Proxeronase to make and/or use the present composition. Undue experimentation is necessary to make or use the present composition commensurate in scope with these claims.

3. Claims 2 and 4-17 are rejected under 35 U.S.C. 112, first paragraph, The specification does not enable any person skilled in the art to which it pertains, or with

Art Unit: 1617

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification, while being enabling for the use of the juice or oil extract of noni, does not enable any person skilled in the art for the use of the other “processed” parts of the plant.

4. Claims 25, 27, and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the specification provides for a skin toner composition comprising 0.1-10 percent by weight of noni oil extract, there is no support for using more than 10 percent by weight of the component as recited by instant claims 25, 27, and 29. See original spec. p. 26, lines 10-12.

B. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 2 and 4-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected as the term “processed *Morinda citrifolia*” renders the claim vague and indefinite. The metes and bounds of the scope of the patent protection sought are unclear.

Claim 13 recites the limitation "said *Morinda citrifolia*" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

The remaining claims are rejected as depending on indefinite base claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1 and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Moniz (US 5288491).

Moniz discloses that noni juice diluted with water, the oil extract for hair application or "mashed fruit" drink has been used as ancient folk medicine in the Pacific. See col. 1, line 40 – col. 2, line 65.

Applicants, in response filed February 28, 2002, argues that the anticipation rejection over Moniz is inappropriate since not every element of the claimed invention is shown in the reference. Specifically, applicants assert that Moniz fails to teach, either expressly or inherently, a cosmetic skin toner composition containing a combination of xeronine and Proxeronase.

Examiner takes the position that the phrase "topical cosmetic skin toner composition designed to hydrate and balance pH levels in said skin" in claim 1 is a mere preamble statements reciting purpose or intended use, and not a claim limitation. It is well settled patent law that, if the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states the purpose or intended use of the invention, rather than any distinct definition of any of the claimed

invention's limitation, then the preamble is not considered a limitation and is of no significance to claim construction. See *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F. 3d 1298, 1305, 51 U.S.P.Q. 2d 1161, 1165 (Fed. Cir. 1999). It is also held that if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See *In re Schreiber* 128 F.3d 1473, 1477, 44 U.S.P.Q. 2d 1429, 1431 (Fed. Cir. 1997). See also MPEP 2112.02. In this case, the only structural limitation in claim 1 is a composition comprising xeronine and Proxeronase in 0.001-80 percent by weight and a cosmetically suitable carrier. The presence of xeronine and Proxeronase in the noni juice diluted with water as disclosed in Moniz, is inherent. See Moniz, col. 3, lines 1 – 18. The wide weight limitation of the xeronine and Proxeronase of the instant claims is considered met by the prior art, unless proven otherwise.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, and 4-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kondo (JP 200095663A, machine translation) in view of Duffy et al. (US 5472699).

Kondo teaches cosmetic composition comprising plant extracts which provide skin whitening, oxygen scavenging and/or antimicrobial effect. *Morinda Citrifolia* (noni) is among the plant extracts disclosed in the reference. See translation, paragraphs [0001- -0009]. Kondo further teaches the invention may be formulated into various types of cosmetic compositions, including skin care lotion and face toilet, which is considered as a skin toner product. See translation, paragraph [0017]. The whitening

Art Unit: 1617

effect of Mulberry bark extract (which is deemed to be noni) is also discussed in paragraphs [0025-36] and Table 2. The reference further teaches that the cosmetic compositions may include the additives that meet instant claims 19-26.

While the cosmetic formulation in Kondo contains 4.8 % of *Morinda citrifolia* (noni), differences in concentration in general will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Kondo, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation. Increasing the concentration of noni would be desirable to enhance the whitening, antioxidant, and antibacterial effect of the composition.

While the example composition in Kondo contains the bark extract of noni, examiner takes the position it would have been obvious to a skilled artisan that other parts of the same plant would inherently provide the same effects.

Duffy teaches a cosmetic composition comprising botanical astringent comprising extracts from Witch Hazel, Linden which is a source of vitamin C, E, and farnesol, and St. John's Wort which is a source of vitamin A. Employing silica, water, ethyl alcohol (denatured alcohol), glycerin, pyridoxine HCL, fragrances, thickeners, preservatives, and colorants are also disclosed. The reference teaches that the invention helps reduce the size of pore of the skin and control sebum secretion.

Given the general teaching of making cosmetic compositions from noni in Kondo, one of ordinary skill in the art at the time the invention was made to have looked to prior

arts such as Duffy for specific additive components suitable for botanical astringents and modified the composition of Kondo by incorporating such additives because of the expectation of successfully producing a skin care composition that improves skin appearance by whitening the skin, reducing the pore size and controlling oil secretion, and/or provides antiseptic effect.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
May 16, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200